PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Van Dyke *et al*.

Serial No.: Unknown (Cont of 09/330,550)

Filed: Concurrently

For: SOLUBLE KERATIN PEPTIDE

Group Art Unit: Unknown

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PRELIMINARY AMENDMENT

BOX PATENT APPLICATION

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

Please enter the following amendment.

Please cancel claims 1-54 without prejudice or disclaimer.

Please add the following claims:

55. A composition comprising water soluble peptides, wherein said peptides are obtained by:

oxidizing human or animal hair, human or animal nails, fur, hooves, or feathers, in an aqueous oxidizing solution;

filtering said aqueous oxidizing solution to obtain a water soluble portion;

substantially neutralizing said water soluble portion; and

adding a water-miscible organic solvent to said water soluble portion, such that a precipitate is formed;

wherein said precipitate comprises water soluble peptides.

- 56. The composition of claim 55, further comprising the step of drying said precipitate to obtain a powder.
- 57. The composition of claim 55, wherein said oxidizing includes placing said hair, hooves, feathers, or human or animal nails in a solution comprising an oxidizing agent selected from hydrogen peroxide, peracetic acid, a percarbonate, a persulfate, chlorine dioxide, sodium peroxide, calcium peroxide, a perborate, or hypochlorite.
- 58. The composition of claim 55, wherein said oxidizing includes suspending said hair or feathers in a solution comprising from about 1 to about 32 volume percent peracetic acid or hydrogen peroxide.
- 59. The composition of claim 55, wherein said water-miscible organic solvent is methanol, ethanol, acetone, tetrahydrofuran or a combination thereof.
- 60. The composition of claim 55, wherein said water-miscible organic solvent is methanol.
- 61. The composition of claim 55, wherein said water-miscible organic solvent is ethanol.
- 62. The composition of claim 55, wherein said water soluble portion is concentrated up to about 10 fold prior to adding said water-miscible organic solvent.
- 63. The composition of claim 55, wherein said water-miscible organic solvent is added at a volume ratio of organic solvent to aqueous solution of from about 60:1 to about 100:1.

- 64. The composition of claim 62, wherein said water-miscible organic solvent is added at a volume ratio of organic solvent to aqueous solution of from about 6:1 to about 10:1.
- 65. The composition of claim 55, wherein the process comprises oxidizing human hair in an aqueous oxidizing solution.
- 66. The composition of claim 55, wherein at least about 90% of said water soluble peptides are between about 300 and about 1300 daltons in molecular weight.
- 67. The composition of claim 55, wherein said water soluble peptides have a mean molecular weight of about 850 daltons.
- 68. The composition of claim 55, wherein said water soluble peptides comprise from about 3.8 to about 4.78 weight percent sulfur.
- 69. The composition of claim 55 wherein said precipitate is contained in a gel, lotion, paste, cream, or aqueous solution.
- 70. The composition of claim 55, wherein said precipitate is a component of a wound dressing.
- 71. The composition of claim 70, wherein said wound dressing is a sheet comprising a keratin derived product.
- 72. The composition of claim 70, wherein said wound dressing is an adhesive bandage.
- 73. The composition of claim 55, wherein said precipitate is a component of a tissue engineering scaffold.

- 74. The composition of claim 73, wherein said tissue engineering scaffold comprises an insoluble keratin derived product.
- 75. The composition of claim 55, wherein said precipitate is contained in or associated with a hydrogel.
- 76. The composition of claim 75, wherein said hydrogel comprises a keratin derived hydrogel.
- 77. A composition for topical application to skin of a human or animal subject, said composition comprising the soluble peptides of claim 55, contained in a lotion, gel, paste, cream, or aqueous solution.
- 78. The composition of claim 77, wherein said water soluble peptides are obtained from human hair.
- 79. The composition of claim 78, wherein said human hair is the hair of said human subject.
- 80. The composition of claim 77, wherein said skin is damaged skin.
- 81. The composition of claim 80, wherein said damaged skin includes a wound, a rash, diaper rash, a burn, a sunburn, a cut, an abrasion, a puncture, a sore, a bedsore, an ulcer, or wrinkled skin.
- 82. A method of treating damaged epithelial tissue of a human or animal subject comprising contacting said damaged epithelial tissue with the composition of claim 77.
- 83. The method of claim 82, wherein said damaged epithelial tissue includes a wound, a rash, diaper rash, a burn, a sunburn, a cut, an abrasion, a puncture, a sore, a bedsore, an ulcer, or wrinkled skin.

- 84. The method of claim 82, wherein said water soluble peptides are obtained from human hair.
- 85. The method of claim 84, wherein said human hair is the hair of said human subject.
- 86. A wound dressing comprising the composition of claim 55 contained in, or adhered to a sheet, film or fabric dressing.
- 87. The wound dressing of claim 86, wherein said sheet, film or fabric comprises a keratin derivative.
- 88. The wound dressing of claim 86, wherein said wound dressing is an adhesive bandage.
- 89. A cell growth scaffold comprising a keratin derived sheet material, porous material or hydrogel, and further comprising a composition of claim 55 contained in, or adhered thereto.
- 90. A composition for the promotion of healing of damaged epithelial tissue comprising the composition of claim 55 contained in a hydrogel.
- 91. The composition of claim 90, wherein said hydrogel is a keratin hydrogel.
- 92. The composition of claim 90, wherein said epithelial tissue is skin, nasal, oral, gastro-intestinal, anal, vaginal, ear, eye, lung, or urogenital epithelial tissue.
- 93. A composition for topical application to skin of a human or animal subject, wherein said composition comprises the powder of claim 56.
- 94. The composition of claim 93, wherein said powder is mixed with an absorbent material.
- 95. The composition of claim 93, wherein said powder is mixed with a non-absorbent material.

96. The composition of claim 95, wherein said non-absorbent material is a water insoluble keratin powder.

A check in the amount of \$543.00 is enclosed herewith for the filing fee of the concurrently filed continuation application. No further fees are believed to be due with the filing of this amendment. If any fees are deemed to be required under 37 C.F.R. §§ 1.16 to 1.21 for any reason relating to the enclosed materials, the Assistant Commissioner is hereby authorized to deduct said fees from VINSON & ELKINS L.L.P. Deposit Account No. 22-0365/KER020/4-005CON.

Respectfully submitted,

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